REMARKS

Claims 2-12 and 15-19 are all the claims pending in the application. Upon entry of the claim amendments, claims 2-6, 12, 15-17 and 19-20 are pending, and claims 7-11, 13-14, and 18 are canceled. Claims 2-6, 12, 15-16, and 19 are amended, and Claim 20 is newly added. Support for claim amendments and new claim 20 may be found in original claims and throughout the specification.

Claims 2-4 have been amended to delete various members of the Markush groups of substituents.

Claim 5 has been amended to depend from claim 4, instead of 3.

Claim 6 has been amended to specify the a hydrazine aminating agent as the formula $H_2N\text{-}NR_{14}R_{15}$. Support for this claim amendment can be found at least at pages 4-5 and in Example 1.

Claim 12 has been amended to delete the recitations of "prevention," "amelioration," and "derivative."

Claim 15 has been amended to recite "[a] method for the treatment of inflammation, comprising the step of administering to a patient … ." Support for this claim amendment can be found at least at pages 32-33, pages 40-41, in Example 3 and in Figures 1-4.

Claim 16 has been amended to delete the recitation of "derivative."

Claim 19 has been amended to clarify the claim language by reciting "and pharmaceutically acceptable salts thereof."

Claim 20 has been introduced to specify the cancer recited in Claim 12 to be prostate cancer, breast cancer, or large cell lung cancer. Support for new claim 20 can be found at least at pages 31-32 and in Example 3.

Accordingly, no new matter has been introduced by these amendments to the claims.

Claim to Priority

In the Office Action Summary, the Examiner has not acknowledged Applicants' claim to priority or receipt of the certified copy of the priority document. At page 1 of the Office Action, the Examiner has acknowledged Applicants' claim to priority but failed to acknowledge receipt of the certified copy of the priority document filed on April 21, 2005.

Accordingly, Applicants respectfully request that the Examiner acknowledge receipt of the priority document, which was received by USPTO on April 21, 2005.

Claim Rejections-35 U.S.C. § 101

Claim 2 is rejected under 35 U.S.C. § 101 because Claim 2 has been amended to contain a proviso that allegedly does not have support in the originally filed specification.

Without acquiescing in the merits of the rejection, claim 2 has been amended to delete the recitation of the proviso.

Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. § 101 be reconsidered and withdrawn.

Claims Rejections-35 U.S.C. § 112

1. Claims 7, 8, 12 and 15 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner asserts that the specification does not reasonably provide enablement for preventing diseases.

The Examiner further states that this rejection can be overcome by amending the claims to exclude "prophylaxis" or "prevention" of diseases as recited in the claims.

Without acquiescing in the merits of the rejection, claims 7-8 have been canceled and claims 12 and 15 have been amended to exclude "prophylaxis" or "prevention" of diseases as suggested by the Examiner.

Applicants therefore respectfully request that this rejection under 35 U.S.C. § 112 be reconsidered and withdrawn.

2. Claims 7-12 and 15 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner asserts that the specification does not adequately describe the nexus between the cellular activity of the instant compounds and a useful treatment of a disease/condition.

Applicants disagree, and traverse the rejection, respectfully, in view of the following remarks.

Without acquiescing in the merits of the rejection, claims 7-11 are canceled. Claims 12 and 15 are amended to recite methods for the treatment of cancer and inflammation, respectively.

Applicants respectfully assert that the Office Action failed to establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. As noted in MPEP § 2163.04, "a description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. *See, e.g., In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The Examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The Examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976)," (emphasis added).

Nevertheless, the Examiner merely alleges, without any reasonable basis, that the Specification does not provide written description of the claimed methods for the treatment of cancer and inflammation. The only basis provided in the Office Action is that the Specification allegedly does not adequately describe the nexus between the cellular activity of the instant compounds and a useful treatment of a disease/condition.

In response, Applicants respectfully direct the Examiner to Page 32, line 23-page 33, line 16 and Example 3. The specification sufficiently demonstrates the effect of the claimed compounds in the cyclooxygenases (COX) modulation in Example 3 and explains the use of COX modulation for anti-cancer treatment and as an anti-inflammatory. See Page 32, line 23-page 33, line 16, pages 40-41, Example 3 and Figures 1-4. Thus, the specification indeed provides ample support for the nexus between the cellular activity of the chemical structures,

formulas (III) and (VIII), and the recited conditions, cancer and inflammation, as recited in claims 12 and 15.

For the reason set forth above, Applicants submit that the specification is replete with support for the full scope of the claimed invention, such that one of skill in the art would understand that the inventor had possession of the full scope of the invention at the time of filing.

Applicants therefore respectfully request that this rejection under 35 U.S.C. § 112 be reconsidered and withdrawn.

3. Claims 7-12 and 15 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Applicants respectfully disagree and assert that the Specification provides enabling support.

Without acquiescing in the merits of the rejection, claims 7-11 are canceled. Claims 12 and 15 are amended to recite methods for the treatment of cancer and inflammation, respectively.

In making the rejection, the Examiner asserts that it would require undue experimentation for one of skill in the art to test which diseases can be treated by the claimed compounds. Amended claims 12 and 15 recite specific conditions, cancer and inflammation. Thus, one of ordinary skill in the art would understand which conditions can be treated by the claimed compounds without undue experimentation.

Additionally, the Examiner states, "one of ordinary skill in the art is unable to fully predict possible results from the administration of the compound of claim 1 due to the unpredictability of the role of modulation of androgen receptors." In response, Applicants

point out that the present specification sufficiently teaches roles of modulation of androgen receptors and the effect of androgen receptor modulation in the treatment of the recited cancer and inflammation.

Specifically, Applicants respectfully direct the Examiner to Examples 2 and 3. In Example 2, testosterone has been added to a cell culture medium, which resulted in an abnormal rate of growth. Administration of the claimed compound is shown to inhibit cell proliferation. *See* Example 2 and Figure 2. In Example 3, treatment with the claimed compound results in inhibition of thromboxane synthase (TBXZ) and cyclooxygenases (COX), which is well-known in the art to be related to cancer initiation and inflammation. *See* Page 32, line 23-page 33, line 16 and Example 3. Thus, from reading the specification, one of ordinary skill in the art would be able to conclude, without undue experimentation, that the claimed compounds have anti-cancer and anti-inflammation effects. Furthermore, the present specification provides ample guidance regarding how to bring the claimed compound into contact with cancerous tissue in a mammal and how to administer the claimed compound to a patient as recited in Claims 12 and 15, respectively. Pages 18-23.

For the reasons set forth above, Applicants submit that the specification enables one of ordinary skill in the art to treat the recited conditions by administering the claimed compound without undue experimentation. Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. § 112 be reconsidered and withdrawn.

4. Claims 6-8, 12 and 15 are rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Without acquiescing in the merits of the rejection, Claims 7-8 are canceled. Regarding the remaining claims, Applicants disagree, and traverse the rejection, respectfully, in view of the following remarks.

With respect to claim 6, the Examiner alleges that the claim is missing essential steps for the process for the preparation of a compound of formula (III) or (VIII). In response, Applicants have amended claim 6 to recite "the step of reacting the 4-keto group of a compound of the formula (X) ... with a hydrazine aminating agent of formula $H_2N\text{-}NR_{14}R_{15}$."

With respect to claims 12 and 15, the Examiner questions the extent of "ameliorate." In response, Applicants have amended claims 12 and 15 to delete the recitations of "amelioration."

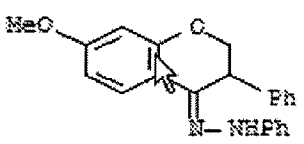
Moreover, with respect to claim 15, the Examiner questions whether the claim is drawn to a method of treating or a pharmaceutical composition. In response, Applicants have amended claim 15 to recite "[a] method for the treatment."

Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. § 112 be reconsidered and withdrawn.

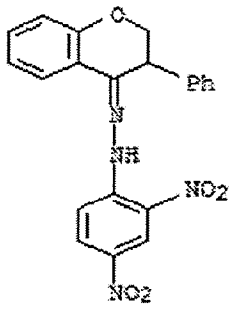
Claims Rejections-35 U.S.C. § 102

Claims 2-12 and 15-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue (CA 58:33237 & CA 58:33236), Donnelly, Ramanujam, Lebreton, Fukami, Cieslak and Bradbury.

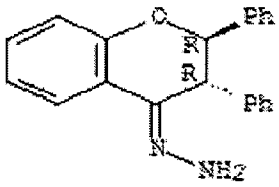
The Examiner asserts that Inoue [1-a and b], Donnelly [2], Ramanujam [3], Lebreton [4], Fukami [5], Cieslak [6] and Bradbury [7] teach the following five compounds.



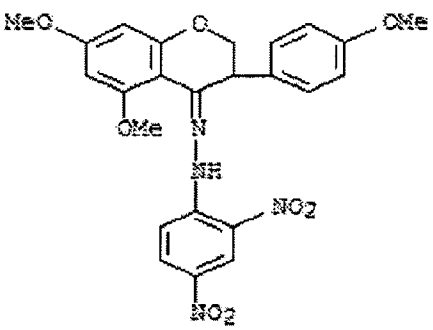
[1-a]



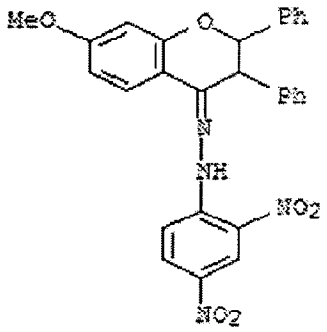
[1-b]



[2]



[3, 4 and 7]



[5 and 6]

Applicant respectfully disagrees. As pointed out in MPEP § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim." Thus, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. Of California*, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987)." Applicant respectfully asserts that the Office Action failed to provide a prior art reference that teaches every element as set forth in the claim.

Without acquiescing in the merits of the rejection, claims 7-11 and 18 are canceled. Independent claim 2 has been amended to delete various members of the Markush groups of substituents, and claims 3-6, 12 and 15-17 depend directly or indirectly from independent claim 2. Applicants assert that the amendments to claim 2 render moot all outstanding claim

rejections to claims 2-6, 12 and 15-17, because the cited art fails to disclose the claimed compound as recited in claim 2.

Regarding claim 19, Applicants note that none of cited references discloses 4',7-dihydroxy-4-methylimino-isoflavan (11), 4',7-dihydroxyisoflavanone oxime (12), 4-amino-3',4'-dimethoxy-7-hydroxy-8-methylisoflavan (13), or N-[3',4'-dimethoxy-7-hydroxy-8-methyl-4-chromanyl)-acetamide (14) as recited in the claim. Page 16 of the Specification.

Accordingly, Applicants respectfully request that this rejection under 35 U.S.C. § 102 be reconsidered and withdrawn.

Claim Objections

At page 14 of the Office Action, item 11, the Examiner objected claims 3, 5-6, and 18-19 because of the following informalities.

(1) Claims 3 and 6 depend from claim 1 which is canceled.

(2) Claim 5 depends from claim 34. There is no claim 34.

(3) Claim 18 must be complete as written. The Examiner requests Applicants to identify by name or structure the compounds that are encompassed by claim 18.

(4) Claim 19 has a phrase "which compounds include". The Examiner requests Applicants to clarify the meaning of the phrase.

In response, Applicants have amended claims as follows:

(1) Claims 3 and 6 depend from claim 2.

(2) Claim 5 depend from claim 4.

(3) Claim 18 has been canceled.

(4) Claim 19 has been amended to replace the phrase "which compounds include" with "and." Support for the claim amendments can be found at least in page 16, lines 5-6.

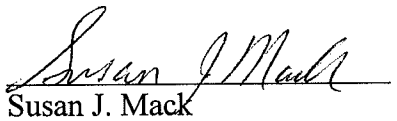
Accordingly, Applicants respectfully request that this objections to the present claims be reconsidered and withdrawn.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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Date: April 16, 2009